disclaimer. Applicant reserves the right to file a divisional application directed to any cancelled subject matter.

Applicant notes that claims 74-76 are grouped in both Group III and Group IV. It appears that these claims properly belong in Group III, drawn to methods of treatment, prevention, or amelioration of one or more symptoms of bronchoconstrictive disorders. Thus, Group IV should include claims 71-73. Appropriate correction of the restriction requirement is respectfully requested.

TRAVERSAL OF RESTRICTION REQUIREMENT

Applicant traverses the Restriction Requirement as between Group I and Group II (in part), and as between Group I and Group IV. It is respectfully submitted that Group I is related to each of Groups II (in part, claims 65-67, 92 and 93) and IV as a subcombination/combination for which a showing of two-way distinctness is required.

Restriction of Groups I and II (in part)

Inventions that are related as a combination and subcombination are distinct and restriction may be proper **only if** it can be shown that the combination as claimed does not require the particulars of the subcombination as claimed for patentability **and** that the subcombination has utility by itself or in other combinations. See MPEP 808.05(c).

It is first noted that instant claims 65-67, 92 and 93, placed in Group II, are not directed to kits, but rather are directed to combinations of the pharmaceutical compositions of Group I and a vial. In this instance, patentability of the combination, the combinations containing a pharmaceutical composition and a vial of claims 65-67, 92 and 93 of Group II, require the particulars of Group I (the compositions) for patentability. If the compositions of Group I are deemed free of the prior art, the combinations of Group II, which contain the compositions of Group I, will necessarily be free of the prior art. Therefore, the combinations of claims 65-67, 92 and 93 of Group II and compositions of Groups I are not distinct.

If the claims are restricted into these two groups, applicant ultimately could be granted two patents, one that includes claims encompassing pharmaceutical compositions, and another with claims directed to combinations containing the compositions, that expire on different dates. If the claims to the combinations (combinations containing a composition and a vial) issued first, a later issuing patent encompassing the subcombination (compositions) could not be held to constitute obvious-type double patenting over the earlier issuing patent. See MPEP 806, paragraph 3, which states:

> [w]here inventions are related as disclosed but are not distinct as claimed, restriction is never proper. Where restriction is required by the Office double patenting cannot be held, and thus, it is imperative the requirement should never be made where related inventions as claimed are not distinct.

See, also MPEP 804.01, which states:

> 35 U.S.C. 121 authorizes the Commissioner to restrict the claims in a patent application to a single invention when independent and distinct inventions are presented for examination. The third sentence of 35 U.S.C. 121 prohibits the use of a patent issuing on an application with respect to which a requirement for restriction has been made, or on an application filed as a result of such a requirement, as a reference against any divisional application, if the divisional application is filed before the issuance of the patent. The 35 U.S.C. 121 prohibition applies only where the Office has made a requirement for restriction. The prohibition does not apply where the divisional application was voluntarily filed by the applicant and not in response to an Office requirement for restriction. This apparent nullification of double patenting as a ground of rejection or invalidity in such cases imposes a heavy burden on the Office to guard against erroneous requirements for restrictions where the claims define essentially the same invention in different language and which, if acquiesced in, might result in the issuance of several patents for the same invention.

The Office Action alleges that Groups I and II are independent and distinct because they allegedly have different classifications. As noted above, instant claims 65-67, 92 and 93, placed in Group II, are not directed to kits, but rather are directed to combinations of the pharmaceutical compositions of Group I and a vial. It is respectfully submitted that the combinations of instant

claims 65-67, 92 and 93 have not been properly classified. Since restriction of Group I and claims 65-67, 92 and 93 of Group II is improper, reconsideration and withdrawal of the restriction requirement as between Group I and claims 65-67, 92 and 93 of Group II is, therefore, respectfully requested.

Restriction of Groups I and IV

As noted above, inventions that are related as a combination and subcombination are distinct and restriction may be proper **only if** it can be shown that the combination as claimed does not require the particulars of the subcombination as claimed for patentability **and** that the subcombination has utility by itself or in other combinations. See MPEP 808.05(c).

In this instance, patentability of the combination, the articles of manufacture of Group IV, which contain a pharmaceutical composition of Group I, require the particulars of Group I (the compositions) for patentability. If the compositions of Group I are deemed free of the prior art, the articles of manufacture of Group IV, which contain the compositions, will necessarily be free of the prior art. Therefore, the articles of manufacture of Group IV and compositions of Group I are not distinct.

If the claims are restricted into these two groups, applicant ultimately could be granted two patents, one that includes claims encompassing pharmaceutical compositions, and another with claims directed to articles of manufacture containing the compositions, that expire on different dates. If the claims to the combinations (articles of manufacture) issued first, a later issuing patent encompassing the subcombination (compositions) could not be held to constitute obvious-type double patenting over the earlier issuing patent. See MPEP 806, paragraph 3, *supra*. See, also MPEP 804.01, *supra*.

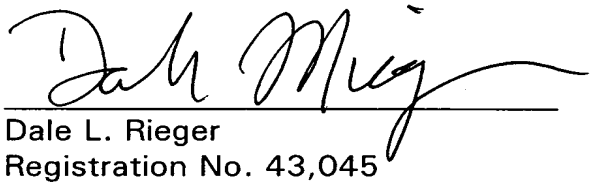
As noted above, if the pharmaceutical compositions of Group I are deemed free of the prior art, then the articles of manufacture of Group IV, which contain the pharmaceutical compositions of Group I, will necessarily be fee of the prior art. Since restriction of such Groups is improper,

reconsideration and withdrawal of the restriction requirement as between Group I and Group IV is, therefore, respectfully requested.

* * *

In view of the above remarks, reconsideration of the restriction requirement and allowance of the application are respectfully requested.

Respectfully submitted,
HELLER EHRMAN WHITE & McAULIFFE LLP

By: 
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